PHARMACEUTICAL REGULATORY AUTHORITY

GUIDELINES FOR DRUG DONATIONS (INCLUDING ARVs) TO THE REPUBLIC OF ZAMBIA

February 2005

FOREWORD

The health sector in Zambia has for many years been receiving drug donations from several bilateral and multilateral development partners. Donations have largely included health commodities, development loans, grants and other forms of assistance. These forms of assistance have immensely contributed to the enhancement of the health care delivery system in Zambia.

In 1998, Zambia launched the National Drug Policy (NDP) to manage and co-ordinate the pharmaceutical supply system and to more rationally coordinate health resources. In addition, the Zambia National Formulary Committee (ZNFC) has developed and disseminated the Standards Treatment Guidelines (STG) and the National Essential Medicines List (NEDL) for use by the public health sector in diagnosing and dispensation of drugs. The NEDL is now in the process of publishing the Zambia National Formulary (ZNF).

Experience demonstrates that some donations had contained in number of products that were not appropriate and usable. Consequently, these Guidelines, that are based on the National Drug Policy and are in line with WHO Guidelines for Drug Donations, are aimed at improving the supply management systems and quality of drug donations in support of the health sector vision of brining quality and affordable health care as close to the Zambian family as possible.

These guidelines define administrative procedures for those who intend to donate drugs to Zambia. They also provide procedures for recipient organizations and Government Ministries in their quest to effectively manage drug donations. It is, therefore, my sincere hope that they will be found helpful in addressing any inconveniences that might have existed in the past.

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INTRODUCTION

The vision of the National Drug Policy is to improve access to good quality, effective, safe and affordable essential drugs (medicines) as close to the family as possible. In this regard the Government is determined to ensure that there is an orderly and effective logistics management supply system for the coutnry's pharmaceutical supply chain, in support of improved health care delivery. This commitment is demonstrated in various elements of the National Drug Policy. To this extent, the Zambia National Formulary, National Essential Medicines List and Standard Treatment Guidelines that are meant to promote rational drug selection and utilization have been developed / revised and disseminated nation-wide.

The Zambian public sector has for many years been receiving drug donations and other forms of health commodities from various multilateral and bilateral agencies, religious organizations, and non-governmental organizations (NGOs). Some of the donations came unsolicited, while others were found to be unusable and delivered very close to their expiry dates; or even already expires. In certain cases, the packaging of the products were very poor and lacked supporting drug information or not in the language known to Zambian health workers.

Given this background, the Government is committed to raising donor / public sector awareness in regard to the acceptable standards that have to be met by all donors of drugs. It is equally committed to raising drug awareness among recipient organizations and consumers. Finally, it is expected that these guidelines will assist in enhancing the procurement, storage and dispensation of drugs as close to the Zambian family as possible.

GUIDELINES FOR DRUG DONATIONS

1.0. Selection of drugs:

- All drug donations should be based on an expressed need and be relevant to the disease pattern in Zambia. The recipient of the drug donation should specify their needs well before the intended donation is sent. Drugs should not be sent without prior consent by the recipient.

- The donation should be in line with the Zambian Essential Drugs List a copy of which may be obtained from the Central Board of Health. However, exceptions can be made for drugs needed in sudden outbreaks of uncommon or newly emerging diseases.

- The presentation, strength and formulation of donated drugs should be similar to the drugs used in Zambia and as stipulated in the Zambia Essential Drugs List and Standard Treatment Guidelines.

- Restricted drugs containing narcotics and psychotropic substances should be should be imported in accordance with the international Conventions on Narcotics and Psychotropic Substances. Details on this may be obtained from the Pharmacy and Poisons Board Secretariat.

Justifications and Explanations

- This provision stresses the point that it is prime responsibility of the recipient to specify their needs. It is intended to prevent unsolicited donations and donations which arrive unannounced and unwanted. It also empowers the recipient to refuse unwanted gifts;

- It further stresses that drug donations should comply with National Drug Policy and Essential Drugs List. It aims at maximizing the positive impact of the donation and prevents the donation of drugs which are unnecessary and/or unknown in Zambia;

- In acute emergencies the need for prior consent by the recipient may be waived, provided the drugs are amongst those from the WHO Model List of Essential Drugs; and

- An exception can also be made for drugs needed in sudden outbreaks of uncommon emerging diseases, since such drugs may not be approved for use in Zambia.

2.0. Quality Assurance and Shelf-life:

- Donated drugs should be authorised for sale in the country of origin and manufactured in accordance with International Standards of Good Manufacturing Practice. Where necessary World Health Organisation (WHO) type Certificate of pharmaceutical products will be requested as recommended by the World Health Certification Scheme on the quality of pharmaceutical products moving in International Commerce. Where it is not possible to use Certification Scheme, a justification should be given by the donor;

- Drugs that have been issued to patients and then returned to a pharmacy or elsewhere or were given to health professionals as free samples should not be donated to Zambia as their quality is not guaranteed; and

- On arrival in Zambia, the donated drugs should have a remaining shelf life of at least one year and this should be communicated to the recipient well in advance. The date of receipt of the donation should be communicated in advance to enable the recipient plan the receipt of the donation.

Justification and explanation

- This provision prevents double standards: drugs of unacceptable quality in the donor country should not be donated to other countries. Donated drugs should be authorized for sale in the country of origin, and manufactured in accordance with international standards of Good Manufacturing Practice (GMP). Exception may be provided where the drug may not be registered in the country of origin due to inexistence of the disease condition. For example, tropical diseases;

- In acute emergencies the use of the WHO Certification Scheme may not be practical. However, if it is not used, a justification should be given by the donor. When donors provide funds to purchase drugs from local producers, those which comply with national standards should not be excluded on the sole grounds that they do not meet quality standards of the donor country;

- Sometimes patients return unused drugs to a pharmacy to ensure their safe disposal; the same applies to drug samples that have been received by health workers. In most countries, it is not allowed to issue such drugs to other patients, because their quality cannot be guaranteed. For this reason returned drugs should not be donated either. In addition to quality

issues, returned drugs are very difficult to manage at the receiving end because of broken packages and small quantities involved; and

- The provision prohibits the donation of drugs just before their expiry dates. Logistical problems limit immediate distribution of drugs and donation of drugs with a short expiry period may reach the patient after the expiry date. It is important that the recipient is fully aware of the quantities of drugs being donated as overstocking may lead to wastage and irrational use. However possible exceptions may be considered for certain drugs which because of their physical properties are manufactured with a short shelf life of less than 2 years. Medicinal products such as vaccines should only be donated in close collaboration with the Ministry of Health as they require stringent handling.

3.0. Presentation, Packaging and labeling

- All donated drugs should be labeled in English, which is the official language in Zambia. The label on each container should at least contain the International Non-proprietary Name (generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date and in case of injections the route of administrations should be indicated. All drugs should be accompanied by insert drug information and/or;

- As much as possible, donated drugs should be presented in larger quantity units (100 or 1000) and hospital packs; and

- All drugs donations should be packed in accordance with International Shipping Regulations and be accompanied by a detailed packing list. Drugs should not be mixed with other supplies in the same carton.

Justification and Explanation

- All donated drugs, including those under brand name, should be labeled also with their INN or the official generic name. Most training programmes are based on the use of generic names. Receiving drugs under different and often unknown brand names and without the INN is confusing for the health workers and can even be dangerous for patients. In case of injections, the route of administration should be indicated;

- Large quantity packs are cheaper, less bulky to transport and conform better with public sector supply systems in most developing countries. This provision also prevents the donation of drugs in sample packages, which are impractical to manage. In precarious situations, the donations of paediatric syrups and mixtures may be inappropriate because of logical problems and their potential misuse; and

- This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations, as the identification and management of unmarked boxes with mixed drugs is very time and labour intensive. This provision specifically discourages donations of small quantities of mixed drugs. The maximum weight of 50kg ensures that each carton be handled without special equipment.

4.0. Information and Management

- The Republic of Zambia, through the Permanent Secretary, Ministry of Health and the Pharmacy and Poisons Board/Pharmaceutical Regulatory Authority should be informed of all drug donations that are under consideration, or actually underway. The information should extend to delivery dates, port of entry and mode of transport; and

- The donor agency should be prepared to meet the costs of international and local transport, warehousing, port clearance and appropriate storage and handling unless specifically agreed otherwise with the recipient in advance. Similarly, the cost of disposing of a drug donation adjudged to be unsuitable will be borne by the donor.

Justification and Explanation

- Many drug donations arrive unannounced. Detailed advance information on all drug donations is essential to enable the recipient to plan for the receipt of the donation and coordinate the donation with other sources of supply. The information should at least include: the type and quantities of donated drugs including their International Nonproprietary Name (INN or generic name), strength to earlier, dosage form manufacture and expiry date, reference to earlier correspondence (for example, the letter of consent by the recipient); the expected date of arrival and port of entry; and the identity and contact address of the donor;

- This provision is needed in the recipient country to prevent drug donation being priced according to the retail price of the product in the donor country, which may lead to elevated overhead costs for import tax, port clearance and handling in the recipient country. It may also result in a corresponding decrease in the public sector drug budget in the recipient country; and

- This provision prevents the recipient from being forced to spend effort and money on the clearance and transport of unannounced consignments of

unwanted items, and also enables the recipient to review the list of donated items at an early stage.

5.0. Management of Drug Donations

5.1. Responsibilities of the Donor Organizations

- Understand the guidelines on drug donations;
- Donations should not be sent without prior consent;
- Communicate with the recipient organization. A comprehensive list of the donated items should be provided to the recipient;
- Consider financial contribution instead of donation in kind of drugs, since it may be more cost effective to buy products locally;
- Consult the Ministry of Health/Central Board of Health Pharmaceutical Unit for clarifications where necessary;
- Inform the Pharmacy and Poisons Board/Pharmaceutical Regulatory Authority well in advance so as to make the necessary arrangements for inspection of the consignments;
- Except in acute emergencies, all drug donations that will be donated outside these guidelines will not be accepted in Zambia. The donor will be asked to facilitate to ship the consignment to the country of origin or destruction as provided by the Environmental Council of Zambia Guidelines or under supervision of a Pharmacist and Pharmacy & Poisons Board/Pharmaceutical Regulatory Authority.

Responsibilities of the recipients

- Understand the guidelines on drug donations. MoH and P&PB/Pharmaceutical Regulatory Authority are in a position to provide any clarifications;
- Communicate with MoH and Pharmacy and Poisons Board/Pharmaceutical Regulatory Authority on the intended donation before they are dispatched to the beneficiaries. CHAZ institutions should liaise with the CHAZ Secretariat for clearance; and

- A comprehensive list of the donated items should be provided to the recipient.

For any questions and clarifications please contact:-

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